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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,686	03/09/2001	Gary Van Nest	377882000900	9981

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EXAMINER
SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
1635	20

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Appli ation No.	Applicant(s)	
	09/802,686	VAN NEST, GARY	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *24 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-6 and 8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-6 and 8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9, 17* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

An amendment was received and entered as Paper No. 119on 6/24/03.

Claims 1-6 and 8-15 are pending and under consideration in this Office Action.

Rejections Withdrawn

The rejections of claims 1-4, 6, 9, and 10 under 35 USC 102 and claims 5, 8, 11-15 under 35 USC 103 are withdrawn in view of Applicant's amendments.

The rejection of claims 1-6 and 8-10 under 35 USC 112, second paragraph is withdrawn in view of Applicant's amendments.

After further consideration, the rejection of claims 1-6 and 8-15 as lacking enablement is withdrawn. The Declaration of Dr. Van Nest shows that a significant result was achieved by performing the claimed invention as directed in the specification, with the sole difference being that the animals were sacrificed 3 days after viral inoculation in the declaration, whereas the specification teaches sacrifice only 1 day after viral inoculation. The simplest explanation for the disparity in results is that the animals were sacrificed too early in the experiment disclosed in the specification, and insufficient time had passed to adequately stimulate cytokine production and viral suppression.

Claim Objections

Claim 11 is objected to because it is ungrammatical. The word --comprise-- should be substituted for the word "comprises" in the phrase "kit does not comprises".

Claim R jections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, 9, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Krieg et al (US Patent 6,339,068, issued 1/15/02).

Krieg teaches a DNA vaccine for therapeutic purposes, and methods of delivering it nasally. The vaccine may encode a respiratory syncytial virus antigen and comprises at least one immunostimulatory sequence (ISS). See abstract; column 1, lines 12-17; column 3, lines 19-21; column 7, lines 15-18; column 12, lines 41-45; column 14, lines 4, 5, 17, and 18; and claim 27 at column 95. Krieg exemplifies an ISS comprising the sequence 5' GACGTTCC 3', see SEQ ID NO:2 at column 9, line 3. The "therapeutic purposes" is taken to mean for the treatment of an existing infection. Because the polynucleotide encodes an RSV antigen, the method of Krieg does not comprise delivery of an RSV antigen per se. Instead, the antigen is subsequently produced by cells that take up the nucleic acid. The method of Krieg does not require the administration of immunostimulatory cytokines, because these cytokines are released in response to the ISSs. See e.g. column 7, lines 10-32. Claim 10 is included in this rejection because, although Krieg does not explicitly teach reduction of RSV titer,

Krieg teaches all of the steps in the claimed method, so reduction of RSV titer is considered to be inherent in the method.

Thus Krieg anticipates the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krieg et al US Patent (US Patent 6,339,068, issued 1/15/02).

Krieg teaches a DNA vaccine for therapeutic purposes, and methods of delivering it nasally. The vaccine may encode a respiratory syncytial virus antigen and comprises at least one immunostimulatory sequence (ISS). See abstract; column 1, lines 12-17; column 3, lines 19-21; column 7, lines 15-18; column 12, lines 41-45; column 14, lines 4, 5, 17, and 18; and claim 27 at column 95. Krieg exemplifies an ISS comprising the sequence 5' GACGTTCC 3', see SEQ ID NO:2 at column 9, line 3. The "therapeutic purposes" is taken to mean for the treatment of an existing infection. Because the polynucleotide encodes an RSV antigen, the composition of Krieg does not comprise an RSV antigen per se. The method of Krieg does not require the administration of immunostimulatory cytokines, because these cytokines are released in response to the ISSs. See e.g. column 7, lines 10-32. Claim 10 is included in this

rejection because, although Krieg does not explicitly teach reduction of RSV titer, Krieg teaches all of the steps in the claimed method, so reduction of RSV titer is considered to be inherent in the method.

Krieg does not teach the organization of the ISS into a kit.

It would have been obvious to one of ordinary skill in the art at the time of the invention to organize the ISS into a kit because one of skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors. Further, the specification of Krieg would serve as instructions for administration of the ISSs to the respiratory tract.

Thus the invention as a whole was prima facie obvious.

Claims 1, 5, 8 , 11, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krieg et al US (US Patent 6,339,068, issued 1/15/02) in view of Raz et al (US Patent 6,498,148, issued 12/24/02).

The teachings of Krieg are summarized in the rejections above. Krieg also teaches generally that sequences comprising a CpG-S motif are suitable for use in the invention. See column 3, lines 7-29, and paragraph bridging columns 8, and 9.

Krieg does not teach an ISS comprising 5'-TGACTGTGAACGTTCGAGATGA-3', administration of ISSs to the lung, or organization of the ISSs into a kit.

Raz teaches an ISS of the sequence 5'-TGACTGTGAACGTTCGAGATGA-3', and teaches that ISS sequences may be delivered to lung tissue intranasally.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the 5'-TGACTGTGAACGTTCGAGATGA-3' ISS of Raz in the invention of Krieg, because it is an art recognized equivalent inasmuch as it is a polynucleotide that is immunostimulatory. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, MPEP 2144.07 indicates that the selection of a known material based on its suitability for its intended use supports the determination of prima facie obviousness. See also Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). In this case, the sequences of Raz and Krieg et al (371) meet the structural requirements set forth in Krieg (068) fro immunostimulatory sequences, i.e. they meet the criteria required to be a CpG-S motif. See column 3, lines 19-29, and paragraph bridging columns 8, and 9.

It would have been similarly obvious to modify the invention of Krieg by delivering the immunostimulatory composition to the lungs. One would have been motivated to do so because Krieg indicates that any delivery route is acceptable, so long as it is functional (column 11, lines 14-17), and because Raz teaches that delivery of ISSs to the lungs is desirable. Thus one could have delivered ISSs to the lungs in the method of Krieg with a reasonable expectation of success. Further one could consider delivery to the lung to be an art-recognized equivalent of the nasal delivery taught by Krieg inasmuch as Raz teaches that delivery to the lung is accomplished by intranasal delivery (see column 2, lines 21-24).

It would have been obvious to one of ordinary skill in the art at the time of the invention to organize the ISSs into a kit because one of skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors. Further, the specification of Krieg would serve as instructions for administration of the ISSs to the respiratory tract.

Thus the invention as a whole was prima facie obvious.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

DAVE T. NGUYEN
PRIMARY EXAMINER

Richard Schnizer, Ph.D.